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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,947	12/29/2003	Daniel L. Cox	ACS 66148 (1675XDC)	7894

24201 7590 03/17/2008

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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	**PAPER NUMBER**
3738	

MAIL DATE	DELIVERY MODE
03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,947	COX ET AL.	
	Examiner	Art Unit	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-22 and 24-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-20 and 24-33* is/are rejected.

7)☒ Claim(s) *21 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/17/07 has been entered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (5634928) in view of DeMello et al. (5429597). Fischell et al. discloses (Fig. 1) a stent delivery catheter with a guide wire **30** within an inner tube **11** with its lumen extending from the proximal to the distal end and a region for a stent. It can be seen the tip has a tapered end **11B** and has a radiopaque marker **17** attached to the inner tubular member. The system also includes an outer tubular member or sheath **20** that overlies the stent. Fischell also discloses means to move the outer member, col. 5, lines 26-29. However, Fischell et al. fail to disclose the *tip component being attached* or having the radiopaque material compounded with it. DeMello et al. teach that tips for catheters can

be made of polymeric material, such as a poly-ether-block amide compounded with a radiopaque substance, col. 5, lines 6-21. DeMello et al. show (Fig. 2) the tip **35** *attached* to the catheter system and is tapered for good flexibility, col. 6, lines 58-60. It would have been obvious to one of ordinary skill in the art to use a radiopaque substance in a polymer attachable tip as taught by DeMello et al. with the catheter system of Fischell et al. in order to provide a non-movable radiopaque material and provide the ability to use different length tips by using attachable tips.

Claims 17,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. '928 in view of Klemm (5458615) and DeMello et al. '597. Fischell et al. and DeMello et al. are explained above. However, Fischell et al. fails to disclose an attached tip with a polymeric material compounded with it and explicitly the housing or pull-back assembly used to retract the sheath. Klemm teaches (Fig. 12) a housing assembly **51** with a base and a slidable handle **53** thereon. DeMello et al. is explained supra. It would have been obvious to one of ordinary skill in the art to incorporate a pull-back handle assembly as taught by Klemm and an attachable radiopaque tip as taught by DeMello et al. with the catheter system of Fischell et al. such that it gives the surgeon easier manipulation capability and a non-movable tip that is easy to locate since it is radiopaque.

Claims 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (5391172) in view of Maria van Erp (6102891). Williams et al. disclose (Fig. 5) a delivery catheter with an inner tubular member having an inner guide wire lumen for guidewire **145**. Williams also shows the inner member has a region for

mounting a stent **40** and an outer restraining sheath **10**. Fig. 3 shows a handle with a pull-back portion **100** mounted on a base. Williams discloses the handle retracts the sheath, col. 3, lines 14-24. However, Williams et al. fail to disclose the distal mounting region including an opening for fluid flow. Maria van Erp teaches (Figs. 2-4) a plurality of openings **13** formed along the length of the inner tubular member **12** that can allow fluid flow through the openings. Maria van Erp also teaches that the holes are important to allow air or fluid to be removed from the catheter, col. 3, lines 57-63. It would have been obvious to one of ordinary skill in the art to incorporate openings in the distal mounting region to allow fluid flow as taught by Maria van Erp in the catheter of Williams et al. such that no fluid or air can be introduced harmfully to the patient by using the holes to evacuate the lumen.

Claims 18,24,25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. '928 in view of Klemm (5458615) and DeMello et al. '597 and further in view of Maria van Erp '891. Fischell as modified by Klemm and DeMello is explained supra. However, Fischell in view of DeMello fail to disclose the catheter system including means or a syringe to evacuate air from the catheter. Maria van Erp is also explained above. It would have been obvious to one of ordinary skill in the art to utilize air evacuation means as taught by Maria van Erp in the catheter system of Fischell et al. as modified by Klemm and DeMello in order to prevent any air embolis from forming in the bloodstream that resulted from lack of removal from the catheter.

Claims 20,26,27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. '928 in view of Klemm et al. '615 and DeMello et al. '597 and further in

view of Houser (5876369). Fischell as modified by Klemm and DeMello is explained supra. However, Fischell in view of Klemm and DeMello do not disclose the use of $BaSO_4$ in the PEBAX material of the catheter tip. Houser teaches that $BaSO_4$ is incorporated into polymers to provide radiopacity for enhancing fluoroscopic observations when using the system, col. 6, lines 11-19. It would have been obvious to one of ordinary skill in the art to incorporate the specific radiopaque material $BaSO_4$ in a polymer as taught by Houser using the catheter system of Fischell et al. as modified by Klemm and DeMello such that the tip has enhanced visibility for insertion purposes.

Allowable Subject Matter

Claims 21,22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 12/17/07 have been fully considered but they are not persuasive. Applicant argued that the patent to Klemm ‘615 failed to disclose the limitation of the lumen extending the length of the inner member. However, it appears the Applicant has not addressed the rejections of record, since the Examiner did not use Klemm to reject the claims for this limitation, Klemm was only used for the claimed limitation of the housing assembly to control delivery of the stent. The Examiner used the reference to Fischell '928 for claims 17 and 28 which teaches the claimed limitation

of the lumen extending from proximal to distal end of the inner tubular member. The Examiner used Williams '172 for claim 29, not requiring this limitation. Applicant failed to submit any arguments in the amendment dated 12/17/07 pointing out disagreements with the examiner's contentions and provided no discussion of these references applied against the claims, explaining how the claims avoid the references or distinguish from them. Thus, the rejections are maintained.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7:30-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738